

Attachment #2. Coversheet for Reviewers SOP / Manufacturer Insert Comparison

Using the attached form, compare the manufacturer's criteria with the criteria in the laboratory's SOP. If all criteria match, circle "match" for the item. If there is a difference, circle "differences". For any difference, write a brief comment or corrective action below that item. If the test is from the LRN or CDC, please use those documents as the reference documents.

The manufacturer package inserts and Laboratory SOPs have been reviewed.

Paul Elmer 4/6/11
Laboratory Supervisor / Date

Comments:

Wenderson 4/11/11
Laboratory Director / Date

Comments:

Tracy Stale 4/11/11
Quality Assurance Director or Manager / Date

Comments:

Attachment #1 Comparison Documentation Grid

SOP Title / number: <i>MTD</i>		Reviewed by / date: <i>PE 4/6/11</i>
Specimen requirements Specimen type <u>match</u> differences Unacceptable spec.: <u>match</u> differences Testing limitations: coll date to test date match differences transportation match differences storage prior to testing match differences	QC Material: <u>match</u> differences Acceptance Criteria: <u>match</u> differences	Linearity or reportable range Method reportable limits: <u>match</u> differences Processing specimens above upper reportable limit: match differences
SOP Title / number: <i>M6IT 960</i>		Reviewed by / date: <i>PE 4/6/11</i>
Specimen requirements Specimen type <u>match</u> differences Unacceptable spec.: <u>match</u> differences Testing limitations: coll date to test date match differences transportation match differences storage prior to testing match differences	QC Material: <u>match</u> differences Acceptance Criteria: <u>match</u> differences	Linearity or reportable range Method reportable limits: match differences Processing specimens above upper reportable limit: match differences
SOP Title / number: <i>Quant. from Gold</i>		Reviewed by / date: <i>PE 4/6/11</i>
Specimen requirements Specimen type <u>match</u> differences Unacceptable spec.: <u>match</u> differences Testing limitations: coll date to test date <u>match</u> differences transportation <u>match</u> differences storage prior to testing <u>match</u> differences	QC Material: <u>match</u> differences Acceptance Criteria: <u>match</u> differences	Linearity or reportable range Method reportable limits: <u>match</u> differences Processing specimens above upper reportable limit: match differences

5/3/2010

Attachment #1 Comparison Documentation Grid

SOP Title / number: <i>Backs SIRE Testing</i>		Reviewed by / date: <i>PE 4/6/11</i>
Specimen requirements	QC	Linearity or reportable range
Specimen type <u>match</u> differences	Material: <u>match</u> differences	Method reportable limits: <u>match</u> differences
Unacceptable spec.: match differences		
Testing limitations: coll date to test date match differences	Acceptance Criteria: <u>match</u> differences	Processing specimens above upper reportable limit: match differences
transportation match differences		
storage prior to testing match differences		
SOP Title / number: <i>MGT 960 P2A</i>		Reviewed by / date: <i>PE 4/6/11</i>
Specimen requirements	QC	Linearity or reportable range
Specimen type <u>match</u> differences	Material: <u>match</u> differences	Method reportable limits: <u>match</u> differences
Unacceptable spec.: match differences		
Testing limitations: coll date to test date match differences	Acceptance Criteria: <u>match</u> differences	Processing specimens above upper reportable limit: match differences
transportation match differences		
storage prior to testing match differences		
SOP Title / number: <i>Accurate Testing</i>		Reviewed by / date: <i>PE 4/6/11</i>
Specimen requirements	QC	Linearity or reportable range
Specimen type <u>match</u> differences	Material: <u>match</u> differences	Method reportable limits: <u>match</u> differences
Unacceptable spec.: <u>match</u> differences		
Testing limitations: coll date to test date match differences	Acceptance Criteria: <u>match</u> differences	Processing specimens above upper reportable limit: match differences
transportation match differences		
storage prior to testing match differences		